

## REMARKS

### Summary of Office Action

Claims 29-50 are pending in this application.

The Examiner said applicants' arguments in the September 30, 2008 Reply To Office Action have been fully considered but are not persuasive.

Accordingly, claims 29, 31, 33, 34, 45, 47, 49, and 50 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg et al. U.S. Patent No. 6,807,797 (hereinafter "Forsberg") in view of Szapiro et al. U.S. Patent No. 5,785,683 (hereinafter "Szapiro").

Claims 37-39, 41, 43, and 44 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Szapiro in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Dependent claims 30, 40, and 46 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in view of Geprägs U.S. Patent No. 4,781,701 (hereinafter "Geprägs").

And claims 32, 34-36, 42, 45, and 47-50 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in further view of Tanaka et al. U.S. Patent No. 5,716,339 (hereinafter "Tanaka").

### Summary of Applicants' Reply

Applicants submit concurrently herewith a Request For Continued Examination under 37 C.F.R. § 1.114.

Applicants have amended independent claim 29 to more particularly point out and distinctly claim the subject matter that applicants regard as the invention, and dependent claim 37 has been amended to conform to claim 29.

No new matter has been added.

Reconsideration of this application in view of the amendments and following remarks is respectfully requested.

Rejections of Claims 29, 31, 33, 34, 45, 47, 49, and 50 Under 35 U.S.C. § 103(a)

Claims 29, 31, 33, 34, 45, 47, 49, and 50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg in view of Szapiro.

These rejections are respectfully traversed.

Independent Claim 29

Independent claim 29 has been amended to require “sealing the rear end of the chamber with a second seal structure movable toward the front compartment to force the wet medicament portion into the front compartment to mix with a dry medicament portion as the second seal structure moves toward the front compartment” (emphasis added).

The Examiner said that it would have been obvious to use the seal and barrel structure of Szapiro with the loading method of Forsberg.

The combination of Szapiro’s barrel structure and Forsberg’s method does not meet the requirements of amended claim 29.

As shown in all of Szapiro’s FIGS. 1-7, plug 9 (*i.e.*, the second seal structure) seals the rear end of main body 1, but is not movable.

Plunger 7, which arguably may be considered to be a part of the second seal structure, does not move toward the front compartment to force the wet medicament portion into the front compartment to mix with a dry medicament portion – but to the contrary, moves away from the front compartment (upper chamber 16) to force the liquid into upper chamber 16 to mix with solid material M.

Accordingly, the combination of Forsberg and Szapiro does not result in applicants' invention as defined in amended independent claim 29 and, therefore, claim 29 is not obvious from that combination and should be allowable.

For at least these reasons, dependent claims 31, 33, and 34, which depend either directly or indirectly from independent claim 29, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

#### Independent Claim 45

A) Independent claim 45 requires that both the open front end and the open rear end of the chamber have an open mouth configuration.

Szapiro's disposable syringe has a lower chamber 11 with a lower base 2 and an upper chamber 16 with an upper base 4. The "lower base 2 is open" and the "conical upper base 4 has the coaxial injection nozzle 5" (column 3, lines 17 and 20-21; emphasis added).

The Examiner said that "since injection nozzle 5 is tubular it is considered an open neck" (October 27, 2008 final Office Action, page 5).

This interpretation is completely unreasonable under a "plain meaning" analysis.

Open-mouthed is defined as "having the mouth wide open" (Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> Ed., p. 814).

Conical is defined as “resembling a cone” (*id.* at p. 244). A cone has sides that taper to a point or vertex.

Nozzle is defined as “a short tube with a taper or constriction” (*id.* at p. 796).

As shown in all of Szapiro’s FIGS. 1-7, conical upper base 4 and “outlet nozzle 5” (column 4, line 27) plainly do not form an open mouth configuration.

Indeed, conical upper base 4 and outlet nozzle 5 are for the most part structurally opposite that of an open mouth configuration.

Compare the open end of Szapiro’s lower base 2 of lower chamber 11, which applicants’ acknowledge has an open mouth configuration, with conical upper base 4 and outlet nozzle 5 of upper chamber 16.

No person of ordinary skill in the art would reasonably interpret Szapiro’s upper chamber 16 as having an open mouth configuration.

Moreover, the Examiner’s assertion that lower chamber 11 and upper chamber 16 both have an open-mouth configuration renders meaningless the claim limitation “open-mouth configuration” – and that cannot be. These words must have some meaning.

If the Examiner continues to assert that upper chamber 16 has an open-mouth configuration, applicants respectfully request the Examiner cite evidence showing that a conical base and outlet nozzle as shown in Szapiro’s FIGS. 1-7 is recognized in the art as an open mouth configuration.

B) The Examiner’s assertion of upper chamber 16 having an open-mouth configuration is also unreasonable in view of the definition/usage of “open mouth configuration” in applicants’ specification:

“The embodiment of [applicants’] FIGURES 1 and 2A is advantageous in that it has an open mouth configuration wherein the needle-end of the vial or chamber is not significantly narrowed or tapered.” Applicants’ specification, paragraph 39; emphasis added.

The needle-end of Szapiro’s main body 1 (*i.e.*, upper chamber 16) is significantly narrowed or tapered.

“As shown in [applicants’] FIGURE 9, the chamber 350 has an ‘open mouth’ configuration; *i.e.*, the container itself does not taper substantially as it meets the needle assembly 340 (for example, as compared with the embodiment shown in FIGURE 3A).” Applicants’ specification, paragraph 68; emphasis added.

A comparison of applicants’ FIGURE 3A (which shows a dental cartridge configuration) with FIGURE 9 (which shows an open mouth configuration) makes evident what applicants mean by an “open mouth configuration.”

Szapiro’s conical upper base 4 and outlet nozzle 5 do not even come close to the dental cartridge configuration shown in FIG. 3A – which applicants distinguished from an open mouth configuration – much less the open mouth configuration shown in FIG. 9.

Although claim terms are to be given their broadest reasonable interpretation, this interpretation must be “consistent with the specification” (MPEP § 2111).

Accordingly, applicants submit that Szapiro’s upper chamber 16 does not have an open mouth configuration as required by claim 45 and as defined/used in the specification.

C) Claim 45 also requires “filling the front compartment of the chamber with a dry medicament portion through the open mouth configuration at the front end of the chamber.”

Applicants previously argued that Szapiro does not disclose or suggest in any way the manner in which its upper chamber 16 and lower chamber 11 are loaded with a powdered drug and diluent, respectively.

Applicants also previously argued that Szapiro's upper chamber 16 is not intended to be filled with solid material M through nozzle 5 in view of the very small opening of nozzle 5.

The Examiner said that the opening in nozzle 5 "would not prevent one of ordinary skill in the art from recognizing that Szapiro is capable of being filled through the front" (October 27, 2008 final Office Action, page 5). The Examiner cited Shields U.S. Patent No. 3,807,119 (hereinafter "Shields") to support that assertion.

Shields purportedly discloses filling a syringe barrel 30 with a medicament in powder form through neck portion 34 of barrel 30. Although the opening in neck portion 34 is about half as wide as the opening in the opposite open end 33 of barrel 30, as shown in Shields' FIGS. 1G-1J, loading a medicament in powder form through that opening as purportedly disclosed is not unreasonable.

However, Shields' neck portion 34 does not in any way resemble Szapiro's conical upper base 4 and outlet nozzle 5 of upper chamber 16, and if Szapiro's syringe were drawn to the same scale as Shield's syringe barrel, the size of the opening in neck portion 34 would dwarf the size of the opening in nozzle 5.

Accordingly, Shields does not support the Examiner's assertion that a person of ordinary skill in the art would recognize that Szapiro is capable of being filled through the very small opening in nozzle 5.

Szapiro's nozzle 5, "along with the annular flange 6, defines the coupling for the plugging cone of the injection needle" (column 3, lines 21-22). In other words, the opening in nozzle 5 is designed to receive an injection needle of a syringe.

No person of ordinary skill in the art is going to fill a powdered drug through an opening sized only large enough to receive a syringe needle – particularly in view of the open mouth configuration of lower base 2.

A person of ordinary skill in the art is more likely to recognize that any attempt to fill a powdered drug through the tiny opening in nozzle 5 is likely to clog the opening or, if even possible, would take such an unreasonably long time that no person of ordinary skill in the art would be motivated to do it – again, especially in view of the open mouth configuration of lower base 2.

If the Examiner continues to assert that Szapiro is capable of being filled with a solid material M through nozzle 5, applicants again respectfully request the Examiner cite evidence to support the feasibility of such a virtually impossible method of loading upper chamber 16 through an opening sized to receive an injection needle.

Accordingly, the combination of Forsberg and Szapiro does not result in applicants' invention as defined in independent claim 45 and, therefore, claim 45 is not obvious from that combination and should be allowable.

Dependent claims 47, 49, and 50, which depend from independent claim 45, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

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In sum, applicants respectfully request that the rejections of claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 37-39, 41, 43, and 44 Under 35 U.S.C. § 103(a)

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Szapiro in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Independent Claim 39

Independent claim 39 requires (1) the open front end of the chamber to have an open mouth configuration and (2) the filling of the front compartment of the chamber with a dry medicament portion through a front end of the chamber.

As discussed above with respect to claim 45, Szapiro's upper chamber 16 has no such opening and in effect teaches away from filling upper chamber 16 through the tiny opening in nozzle 5.

Odell purportedly discloses methods of manufacturing drug delivery and drug container devices in clean, substantially particulate-free areas and, accordingly, does not make up for the deficiencies of Forsberg and Szapiro.

The combination of Forsberg, Szapiro, and Odell therefore does not render claim 39 obvious and, thus, claim 39 should be allowable.



For at least these reasons, dependent claims 41, 43, and 44, which depend from independent claim 39, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 37-39, 41, 43, and 44 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 30, 32, 34-36, 40, 42, and 45-50 Under 35 U.S.C. § 103(a)

Claims 30, 40, and 46 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in view of Geprägs. Claims 32, 34-36, 42, 45, and 47-50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in further view of Tanaka.

These rejections are respectfully traversed.

Geprägs was cited because it purportedly discloses a front syringe barrel with a tapered flow path.

Tanaka was cited because it purportedly discloses a rear chamber filled first with a substance and a front chamber filled next with a dry medication.

Accordingly, neither Geprägs nor Tanaka makes up for the deficiencies of Forsberg and Szapiro as discussed above with respect to independent claims 29, 39, and 45.

Thus, any combination of Forsberg, Szapiro, Odell, Geprägs, and Tanaka does not render obvious independent claims 29, 39, or 45.

For at least these reasons, dependent claims 30, 32, 34-36, 40, 42, and 46-50, which depend directly or indirectly from one of claims 29, 39, or 45, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Moreover, amended dependent claim 35, which depends from independent claim 29, requires the dry medicament portion to be tablet sized and operative to fit through the front end of the chamber. Applicants respectfully submit that no "tablet" (as a person of ordinary skill in the art would understand that word) is operative to fit through the opening of injection nozzle 5 of Szapiro's disposable syringe. If the Examiner maintains her rejection of claim 35, applicants respectfully request the examiner to cite evidence of a "tablet" small enough to fit through an opening sized to receive an injection needle of a syringe.

Accordingly, applicants respectfully request that the rejections of claims 30, 32, 34-36, 40, 42, and 45-50 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

The foregoing demonstrates that claims 29-50 are allowable. This application is therefore in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,



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